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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/058,589	04/10/1998	IAN KIMBER	138.41.US01	7637

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/058,589	KIMBER ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-10,21,23,24 and 26-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-10,21,23,24 and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 26, 2004 has been entered.

Note the claims have been examined insofar as they read on the elected species: "dermal inflammatory disorder." (paper No. 11).

Claims Rejection 35 U.S.C. – 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-10, 21, 23, 24 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. (of record) in view of Britigan (Advances in Experimental Medicine and Biology, Vol. 357, page 143-156, 1994), Morinaga Milk Inc. (JP 07-233086), and De Lacharriere et al. (US Patent 5,658,581).

2. Teng et al teach a method of treating dermal inflammatory disorder of human comprising the step of administering a pharmaceutically effective amount of lactoferrin product. See, particularly, page 4, lines 21-30.

3. Teng et al. does not teach expressly the treatment of the particular dermal disorder herein or the employment of biological analog or fragments of lactoferrin.

However, Britigan teaches generally that lactoferrin are known to be useful as an anti-inflammatory agent. See, particularly, page 151, the summary and conclusion. Morinaga Milk Inc. teaches that lactoferrin or its derivatives are known to be useful for treating various skin disorders, including allergic dermatitis. See, the abstract. De Lacharriere et al. teach that lactoferrin is known to be useful for treating or preventing skin inflammation induced by certain cosmetic or pharmaceutical allergen, See, particularly, the abstract, column 3, line 4 bridging column 4, line 39, and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ lactoferrin product for treatment dermal disorder, particularly, skin inflammation, including contact dermatitis or psoriasis. A person of ordinary skill in the art would have been motivated to employ lactoferrin product for treatment dermal disorder, particularly, skin inflammation, including contact dermatitis or psoriasis because lactoferrin is well known to be useful for anti-inflammation, and is further known particularly useful for treatment of skin inflammation, particularly, allergic dermatitis. Regarding the functional limitation in claim 7, i.e., "a local immune response characterized by increased production of TNF-α" and in claim 21, "a dermal inflammatory response that is characterized by accumulation of dendritic cell in lymph nodes", note such limitation is not seen to render the claimed invention any patentable weight since the ultimate method, e.g., administering lactoferrin to person with dermal inflammatory disorder such as contact dermatitis, UV-induced inflammation, psoriasis, skin aging or diaper rash, is not further limited by such functional language. Further, a method for treatment of a symptom would have been reasonably expected to be effective for the treatment of the symptom despite the underline etiology that

causes the symptom. Finally, the optimization of a result effective parameter, e.g., effective amount of therapeutical agent, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. As to the newly added limitation "that is exposed to an allergen," note allergic dermatitis is caused by exposing to allergen.

Response to the Arguments

Applicants' amendments and remarks submitted February 26, 2004 have been fully considered, but are not persuasive for reasons discussed below.

4. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Particularly, take the cited references as a whole, it would have been obvious that lactoferrin is a well-known anti-inflammatory agent useful for alleviate inflammatory symptom regardless the underline etiology, evidenced by the fact that lactoferrin is used for treating both microorganism induced inflammation and allergen induced inflammation.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a composition consisting essentially of lactoferrin) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Particularly, the claims are drawn to a method of treating an allergen-induced inflammatory disorder in a mammal, consisting essentially of the step of administering to a mammal that is exposed to an

allergen a therapeutically effective amount of a lactoferrin product. Any product comprising lactoferrin would be considered as lactoferrin product.

Further, the cited prior arts clearly teach the usefulness of lactoferrin as anti-inflammatory agent without the requirement of combination with other agents. In De Lacharriere et al. (US Patent 5,658,581), lactoferrin is used as the only anti-inflammatory agent. Other components are for the cosmetic purpose, or preservation. In fact, it is the other components present the allergen. Further, whether De Lacharriere et al. have taught that lactoferrin is an alpha-TNF antagonist is not the issue. De Lacharriere teaches lactoferrin is known to be useful for treating or preventing skin inflammation induced by certain cosmetic or pharmaceutical allergen.

For reasons discussed above, the pending claims have been properly rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

S. Wang

Shengjun Wang

SHENGJUN WANG
PRIMARY EXAMINER

May 11, 2004